REMARKS

The applicants appreciate the Examiner's thorough examination of the application and request reexamination and reconsideration of the application in view of the preceding amendments and the following remarks.

The applicants appreciate and thank the Examiner for allowing claims 16-18.

The Examiner objects to the disclosure for the following informalities stating: "Page 4, line 12 of the specification makes reference to U.S. Patent No. '6,105,515' and should instead refer to U.S. Patent No. --6,106,515-- Appropriate correction is required." In response, as shown above under Amendment A, the applicants have corrected the specification to now correctly reference U.S. Patent No. 6,106,515. Accordingly, the Examiner's objection should be withdrawn.

The Examiner rejects claims 1-5 and 10-13 under 35 U.S.C. §102(b) as being anticipated by U.S. Patent Application Publication No. US 2002/0045848 to Jaafar *et al.* The Examiner alleges Jaafar *et al.* discloses each and every element of the applicants' invention as recited in claim 1.

The applicants' claimed endovascular tissue removal device as recited in claim 1 provides a more precise tissue cutting apparatus for endovascular heart valve replacement which is more effective than prior art blade-type tissue cutters. The claimed endovascular tissue removal device provides effective resection even if the valve is heavily calcified or has byproduct tissue, does not require a high rate of rotation, and eliminates the need for precise control. The claimed endovascular tissue removal device is affected by the use of an optical fiber inside a deflectable tip catheter and an expandable balloon which registers the assembly inside the heart for resection by laser ablation as the deflectable tip steers the distal end of the optical fiber.

The claimed endovascular tissue removal device as recited in claim 1 includes: 1) a lumen including a distal steerable tip portion extending from a joint portion; 2) registration means for holding the joint portion fixed in place in the vasculature; and 3) a source of ablation energy in communication with the lumen whereby tissue can be resected by ablation energy as the tip portion is steered within the vasculature. Independent claims 10-16 include these same features.

In contrast, Jaafar *et al.* teaches and discloses an optical tip (36) that is mated to the fiber (32) and is configured to diffuse UV light in forward and sideways directions to illuminate the inner surface of an aneurism. The apparatus as disclosed by Jaafar *et al.* is for treatment of cerebral aneurisms and AVMs and relies on UV radiation propagating from the optical fiber from the proximal end to the distal end which is terminated by optical tip 36. The optical tip as disclosed in Jaafar *et al.* scatters the radiation in different directions to the aneurism's wall and relies on positioning the optical tip inside the aneurism at different distances from the aneurism wall:

> The surface of the optical tip 36 is mated to the fiber 32 and configured so as to diffuse UV light in the forward and side directions to better illuminate the inner surface 72 of the aneurysm 60. The UV radiation propagates in the optical fiber 32 from its proximal end to the distal end which is terminated with the optical tip 36. The optical tip 36 scatters the radiation in different directions to the aneurysm's wall 72. The optical tip 36 is desirably positioned inside the aneurysm 60 at different distances from the aneurysm wall 72. During irradiation of the dome 74 the distance between the optical tip 36 and the inner surface 7 is short, ranging from about one down to zero mm while during irradiation of the neck 66 the optical tip 36 is placed therewithin. (Paragraph 31, pages 2 and 3)

Clearly, Jaafar *et al.* relies on emitting UV radiation from the optical tip (36) and scattering the radiation in different directions and that is desirably positioned inside the aneurism 60. In contrast, the applicants' claimed endovascular tissue removal device as

recited in independent claims 1 and 10-13 includes a lumen with a distal steerable tip portion extending from a joint portion or a lumen with a deflectable tip catheter and utilizes a source of ablation energy in communication with the lumen in which tissue can be resected by ablation energy as the tip portion is steered within the vasculature.

Therefore Jaafar *et al.* fails to teach, suggest or disclose a lumen including a distal steerable tip portion extending from a joint portion or a lumen including a deflectable tip catheter as recited in applicants' claims 1 and 10-13.

Jaafar *et al.* also clearly fails to teach, suggest, or disclose a registration means for holding the joint portion fixed in place in the vasculature. Instead, the alleged registration means of Jaafar *et al.* is a balloon (balloon 21) that serves for occluding an artery during interventional surgical procedures:

> Catheter 16 may, as shown in FIG. 1, also include an expandable balloon 21, which is used for occluding an artery during an interventional surgical procedure. (Paragraph 26)

Accordingly, for the reasons stated above, Jaafar *et al.* does not teach, suggest, or disclose each and every element of the applicants' invention as recited in independent claims 1 and 10-13. Accordingly, claims 1 and 10-13 are allowable and patentable under 35 U.S.C. §102(b) over Jaafar *et al.* Because claims 2-5 depend from claim 1, these claims are allowable and patentable under 35 U.S.C. §102(b) over Jaafar *et al.*

The Examiner rejects claims 1-15 under 35 U.S.C. §102(b) as being anticipated by Edwards *et al.* (U.S. Patent No. 5,366,490).

Edwards *et al.* does not teach, suggest, or disclose a lumen including a distal steerable tip portion extending from a joint portion or catheter including a deflectable tip as recited in applicants' claim 1, 10-13 and 15. Instead, Edwards *et al.* relies on a guide housing (124) and a stylet positioning block (128) that is positioned for axial movement under the action of

a torque and thrust rod (130). The stylet positioning block (128) has a curved stylet lumen containing the stylet (132). The design relies on positioning block and a port (126) to provide for various configurations of the lumen. The tubing is advanced through the positioning block 128, guide tubing 134 and port 126 to direct the stylet into the tissue:

> FIGS. 8 and 9 are cross-sectional, fragmentary representations of an embodiment of the catheter or this invention with a stylet guide system for adjusting the stylet guide angle. The stylet guide housing 124 has stylet port 126. Within the guide housing 124, a stylet positioning block 128 is positioned for axial movement under the action of torque and thrust rod 130. The stylet positioning block 128 has a curved stylet lumen containing the stylet 132. Optionally, a low friction, flexible guide tubing 134 extends from the positioning block 128 to the port 126. In the position shown in FIG. 8, the positioning block 128 is in a retracted position, orienting the stylet to extend at an acute angle "b" of approximately from about 20° and preferably 30° up to 90° with respect to the central axis of the guide housing. Advancement of the stylet 132 through the block 128, guide tubing 134 and port 126 directs the stylet into tissue along the dotted line path 136.
>
> Advancement of the positioning block 128 as shown in FIG. 9 forces the stylet 132 through a curved path having a smaller diameter through guide tubing 134 to the port 126. The stylet 132 is then directed an obtuse angle which can be as high as about 160° with respect to the guide housing axis. Advancement of the stylet through the guide block 128, guide tubing 134 and port 126 in this configuration directs the stylet into tissue along the dotted line path 138. (Col. 8, lines 18-44, emphasis added)

Edwards *et al.* also does not teach, suggest or disclose a source of ablation energy in communication with the lumen whereby tissue can be resected by ablation energy as a tip portion is steered within the vasculature. Instead, the alleged source of ablation energy of Edwards *et al.* cited by the Examiner, namely reference 150 is a control console that is used with a manual control unit that has a pistol grip with a tube leading to the console:

> FIG. 12 is a schematic view of the assembly of the power and control console 150, a manual catheter control unit 152, catheter 154, and power foot control 156 according to this invention. The manual operation of the catheter assembly is controlled from a manual control unit shown in greater detail in FIG. 13, with the power control and temperature

> displays being provided in the control system 150 shown in greater detail in FIG. 14.
>
> FIG. 13 is an isometric representation of an embodiment of a manual control unit of the system of this invention. The manual control unit 152 has a pistol grip 158 with a tube 160 houses RF or microwave power supply cables, temperature sensors, ultrasound transducer power and signal delivery leads, balloon inflation fluid and vacuum lumens. (Col. 11, lines 3-19, emphasis added)

Clearly the pistol as shown in Fig. 13 of Edwards *et al.* is not used for a source for ablation energy in communication with a lumen whereby tissue can be resected by ablation energy as a tip portion is steered within the vasculature.

Accordingly, for at least the reasons stated above, Edwards *et al.* does not teach, suggest, or disclose each and every element of the applicants' invention. Accordingly, claim 1 is patentable and allowable under 35 U.S.C. §102(b) over Edwards *et al.* Because claims 2-9 depend from an allowable base claim these claims are patentable and allowable over Edwards *et al.* Independent claims 10-13, and 15 include similar features as claim 1 and are therefore allowable and patentable over Edwards *et al.* Because claim 14 depends from claim 13, this claim is also allowable and patentable over Edwards *et al.*

The Examiner rejects claim 16 under 35 U.S.C. §102(b) as being anticipated by Stevens (U.S. Patent No. 5,545,214).

Stevens fails to teach, disclose or suggest directing ablation energy through the lumen as recited in applicants' claim 16. Instead, Stevens teach and disclose utilizing a tissue cutter that is made of cutting blades:

> The tissue cutter comprises at least one proximal blade and a cable. The proximal blade (45) comprises a collapsible hinged (30) blade of length varying from about 1.0 to 20 millimeters with sharp cutting surfaces. This range of blade length can vary up or down depending on the size of host and lumen. Alternatively, the proximal blade can comprise a flexible wire capable of high speed rotation which would deliver a cutting contact to the tissue. (Col. 6, lines 33-41, emphasis added)

More proof of using cutting blades for tissue removal as disclosed by Stevens is shown by:

> Additional blades can be attached to the proximal blade to increase the cutting ability of the tissue cutter (FIGS. 5, 6). For example, two shorter approximately 0.5 to 5.0 millimeter distal blades (40) can be attached through melding, hinging, or other connecting methods, to the distal ends of the proximal blade. This blade length range can vary up or down in size depending on the size of host and lumen. (Col. 6, lines 48-53, emphasis added)

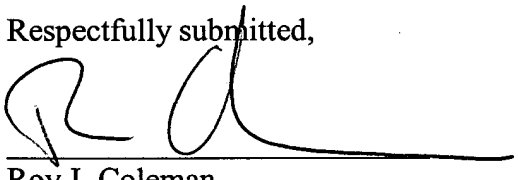
Therefore, Stevens does not teach, suggest or disclose each and every element of applicants' claim 16, namely, directing ablation energy through the lumen, and steering the distal steerable tip portion to resect the valve.

Accordingly, claim 16 is allowable and patentable under 35 U.S.C. 102(b) over Stevens.

Each of the Examiner's rejections has been addressed or traversed. Accordingly, it is respectfully submitted that the application is in condition for allowance. Early and favorable action is respectfully requested.

If for any reason this Response is found to be incomplete, or if at any time it appears that a telephone conference with counsel would help advance prosecution, please telephone the undersigned or his associates, collect in Waltham, Massachusetts, at (781) 890-5678.

Respectfully submitted,



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